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Sunovion Pharmaceuticals Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE: ESZOPICLONE PATENT  
LITIGATION

SUNOVION PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. *et al.*,

Defendants.

**Civil Action No. 09-1302 (DMC) (MF)**

**(Filed Electronically)**

**ORDER OF PERMANENT INJUNCTION**

This action for alleged patent infringement (the "Litigation") has been brought by Plaintiff Sunovion Pharmaceuticals Inc. ("Sunovion") against Defendants Orchid Healthcare (a Division of Orchid Chemicals and Pharmaceuticals Ltd.), Orchid Chemicals and Pharmaceuticals Ltd. and Orgenus Pharma Inc. (collectively, "Orchid") for alleged infringement of United States Patent Nos. 6,444,273, 6,319,926, 6,864,257, and 7,381,724 (collectively, the "Sunovion Patents"). Sunovion's commencement of the Litigation was based on its receipt of notice from Orchid that Orchid had filed ANDA No. 91-113 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed

to the Sunovion Patents and seeking approval to market generic versions of 1, 2, and 3 milligram tablets of eszopiclone.

Sunovion and Orchid have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Sunovion and Orchid during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This reasonable final settlement will afford Sunovion and Orchid the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Sunovion and Orchid acknowledge there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to entry of this Order through a final settlement as reflected herein. The Court, upon the consent and request of Sunovion and Orchid, hereby issues the following Order.

Sunovion and Orchid now consent to this Order of Permanent Injunction and

**IT IS HEREBY ORDERED** that:

1. Subject matter jurisdiction, personal jurisdiction, and venue are all proper in this Court.
2. In this Litigation, Sunovion has charged Orchid with infringement of the Sunovion Patents in connection with Orchid's submission of Abbreviated New Drug Application ("ANDA") No. 91-113 directed to generic tablets containing 1, 2, and 3 milligrams of eszopiclone per tablet to the U.S. Food and Drug Administration ("FDA").
3. In response to Sunovion's charges of patent infringement, Orchid has alleged certain defenses and counterclaims, including that the Sunovion Patents are invalid. The

Court has not adjudicated Sunovion's charges of patent infringement or Orchid's defenses and counterclaims.

4. Orchid has agreed that each of the defenses and counterclaims set forth in its Answer, Affirmative Defenses and Counterclaims, including the allegations and averments contained therein, should be dismissed, without prejudice.

5. Orchid, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic tablet product containing 1, 2, and/or 3 milligrams of eszopiclone per tablet that is the subject of ANDA No. 91-113 until:

(a) The expiration date of U.S. Patent 6,444,673 ("the '673 patent") including a patent term extension pursuant to 35 U.S.C. § 156, minus two and one half months (i.e., November 30, 2013);

(b) in the event that prior to November 30, 2013, the FDA grants pediatric exclusivity for Lunesta®, the expiration date of the '673 patent, including a patent term extension pursuant to 35 U.S.C. § 156, and extended by six months by pediatric exclusivity pursuant to 21 U.S.C. § 355a, minus two and one half months (i.e., May 31, 2014); or

(c) at such earlier date as may be permitted by the Settlement and License Agreement that the Parties have entered into.

6. Sunovion and Orchid each expressly waives any right to appeal or otherwise move for relief from this Order of Permanent Injunction.

7. This court retains jurisdiction over Sunovion and Orchid for purposes of enforcing this Order of Permanent Injunction.

8. The Clerk of the Court is directed to enter this Order of Permanent Injunction forthwith.

**IT IS SO STIPULATED:**

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**SO ORDERED:**

This 23 day of Nov, 2010

  
HONORABLE DENNIS M. CAVANAUGH  
UNITED STATES DISTRICT JUDGE